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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,329

08/01/2003

Paul V. Goode JR.

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KNOBBE, MARTENS, OLSEN & BEAR, LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/633,329	<b>Applicant(s)</b> GOODE ET AL.	
	<b>Examiner</b> ROBERT L. NASSER	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 17-31, 36-48, 50, 55-57, 59, 61, 62, 73-82, 93-136 and 145-170 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 17-31, 36-48, 50, 55-57, 59, 61, 62, 73-82, 93-136 and 145-170 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 12, 14, 17-31, 33, 36-48, 50, 52, 55-57, 59, 61-67, 73-82, 93-113, 116-121, 124-130, 133-147 and 150-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shin et al 2002/0161288 in view of the Mastrototaro article entitled "The Minimed Continuous Glucose Monitoring System" , Millar 6416651, and Say et al 2007/0213610. Shin teaches a method of calibrating and implanted glucose system including the steps of receiving data from both a measuring sensor and a reference sensor to provide a matched pair of time corresponding reference and measuring data points, forming a calibrations et including the at least one pair, converting future sensor data to calibrated data using the calibration set, and displaying the calibrated data. It does not evaluate the quality of the calibration set. Mastrototaro teaches a method of evaluating a calibration set by using a statistical function, i.e. the R Value, data association function to evaluate the data. When the data is above a threshold, Mastrototaro makes notation along with the data to indicate that the data is no accurate. However, Mastrototaro is a retrospective calibration, i.e. it calibrates the data after it has been collected. However, Millar teaches using the R value is a real time or prospective calibration. Hence, it would have been obvious to modify theShin/Mastototaro combination to evaluate the calibration in real time, as it is merely thee substitution of one equivalent calibration technique for another. The combination

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does not provide data only when the threshold is exceeded. However, in Shin, if the calibration fails to meet a certain standard, an error message is supplied. Hence, it is the examiner's position that in the combination, if the calibration does not exceed the threshold, the art would teach to provide such an error message and not the data, to ensure that accurate data is supplied. In addition, the combination does not request additional reference data in response to the calibration. However, in paragraph [0265], Say teaches that when the calibration is not valid, it is known to request additional reference data from the user. Hence, it would have been obvious to modify the combination to request additional reference data, in order to provide for a corrected calibration. Claims 2 and 3 are rejected in that the examiner takes official notice that it is well known to smooth data, to eliminate the effects of anomalous data. As such, it would have been obvious to modify Mastrototaro to smooth the data, to improve the accuracy of measurements. Claims 4-6 are rejected in that Shin receives data from a continuous subcutaneously implantable glucose sensor. Claim 7 is rejected in that the reference sensor is a self test sensor. Claims 8-10 are rejected in that Mastrototaro does not teach how the reference device communicates to the system. The examiner takes official notice that wired and wireless connections are well known and that it would have been obvious to have the receiver integral with the system. Claim 12 is rejected in that Mastrototaro uses a data association function. Claim 14 is rejected in that Mastrototaro teaches the threshold recited in the claims. Claims 17-19 are rejected in that displaying an error message in response to the calibration alters the interface. The exact form of the display would have been a matter of design choice for one skilled in

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the art. Claims 20-31, 33, 36-48, 50, 52, 55-57, 59, 61, and 62 are rejected for the reasons given above. Claims 73 and 74 are rejected in that the method of Mastrototaro is a statistical clinical acceptability analysis. Claims 75-77 are rejected in that Shin further teaches calibrating the device during and after initialization to provide a forward looking calibration, and hence real time data. Hence, it would have been obvious to modify Mastrototaro to use such a calibration scheme, to improve the functionality of the device. In addition, Shin further teaches performing calibration every time a matched pair is obtained (i.e. on a single matched pair) (see paragraph [0069]). Hence, it would have been obvious to modify Mastrototaro to perform calibration every time a pair is obtained, to improve the accuracy of calibration. Claim 78 is rejected in that more than one matched pair can be used. Claims 79-82 and 93-100 are rejected for the reasons given above. Claims 111-113 are rejected in that it is well known to calculate R Value using regression analysis and hence it would have been obvious to do so in the combination. Claims 116 and 177 are rejected in that the system displays an error message. i.e. changes the interface, when error criteria are met. The exact form of the display would have been a mere matter of design choice to one skilled in the art. Claims 118-119 is rejected in that Shin displays calibrated data until an error criteria is met, at which point, the display is stopped and the form of the display is changed. Claims 120, 121, 124-130, 133-136, 145-147, and 150-153 are rejected for the reasons given above. Claim 137 is rejected in that the combination evaluates the quality of the matched pairs. Claims 138-140 are rejected in that Shin, when a calibration error is detected, obtains new pairs, and recalibrates based on the new pairs, then uses the new calibration to

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calculate the data. Claims 141-144 are rejected for the reasons just given. Claim 154 is rejected in that by requesting new reference data, the combination forms a modified calibration set. Claim 155 is rejected in that the new reference data is then used to calibrate the sensor data. Claim 156 is rejected in that Shin uses multi point or single point calibration. Claims 157-163 is rejected for the reasons just given. Claim 165 is rejected in that it seems to the examiner that the entire calibration set would be replaced, which would include removing the oldest pair. Claim 166 is rejected in that the modified data is used to determine a conversion function. Claims 167-170 are rejected for the reasons given above. As to claims 171-173, the combination compares the R value to a threshold, i.e. 0.79. The threshold is based on clinic data.

Claims 114-115, 122, 123, 131, 132, and 148-149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shin et al 2002/0161288 in view of the Mastrototaro article entitled "The Minimed Continuous Glucose Monitoring System," Millar 6416651, and Say, as applied to claims 1-10, 12, 14, 17-31, 33, 36-48, 50, 52, 55-57, 59, 61-67, 73-82, 93-113, 116-121, 124-130, 133-147 and 150-173 above, further in view of the Guerri et al article. Guerri teaches that both R wave and Clarke error grid (i.e. clinical acceptability) are known ways to evaluate a glucose sensor. Hence, it would have been obvious to modify the combination to use both analyses, to provide a more accurate evaluation of the calibration.

Claims 174-176 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shin et al 2002/0161288 in view of the Mastrototaro article entitled "The Minimed Continuous Glucose Monitoring System," Millar 6416651, and Say, as applied to claims

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1-10, 12, 14, 17-31, 33, 36-48, 50, 52, 55-57, 59, 61-67, 73-82, 93-113, 116-121, 124-130, 133-147 and 150-173 above, further in view of the Ham et al 5553616. Ham further teaches that it is known to eliminate outliers from a calibration set (see background section). Hence, it would have been obvious to modify the combination to remove outliers, to improve the accuracy of the results. As to claim 176, removing outliers inherently removes the most discordant value. Since calibration only proceeds when the quality is a sufficient, it is done responsive to the quality of calibration.

Applicant's arguments filed 4/1/2009 have been fully considered but they are not found to be persuasive.

Essentially, applicant has asserted that it would not have been obvious to modify the calibration scheme of Mastrototaro in view of Millar. However, it is the examiner's position that the proposed modification is modifying the calibration scheme of Shin with the combined teachings of Mastrototaro and Millar to evaluate the quality using an R value.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/  
Primary Examiner  
Art Unit 3735

RLN  
June 8, 2009